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MACINTOSH VERSION IS V6.0c(ENG) AND V6.0Jc(JP),
AND CURRENT DISCOVER FILE IS DATED 11 AUGUST 2004
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* * * * * STN Columbus * * * * *

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=> file .gary

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FULL ESTIMATED COST

0.21

0.21

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=> s multikine
L1 16 MULTIKINE

=> dup rem l1
PROCESSING COMPLETED FOR L1
L2 6 DUP REM L1 (10 DUPLICATES REMOVED)

=> d ibib abs 1-6

L2 ANSWER 1 OF 6 MEDLINE on STN DUPLICATE 1
ACCESSION NUMBER: 2004395912 MEDLINE
DOCUMENT NUMBER: PubMed ID: 14576946
TITLE: Histologic and immunohistochemical characterization of
tumor and inflammatory infiltrates in oral squamous cell
carcinomas treated with local **multikine**
immunotherapy: the macrophage at the front line.
AUTHOR: Feinmesser Meora; Okon Elimelech; Schwartz Ariel;
Kaganovsky Ella; Hardy Britta; Aminov Elena; Nageris Ben;
Sulkes Jaqueline; Feinmesser Raphael
CORPORATE SOURCE: Pathology Institute, Beilinson Campus, Rabin Medical
Center, 49100 Petah Tiquva, Israel.. raphael5@barak.net.il
SOURCE: European archives of oto-rhino-laryngology : official
journal of the European Federation of Oto-Rhino-
Laryngological Societies (EUFOS) : affiliated with the
German Society for Oto-Rhino-Laryngology - Head and Neck
Surgery, (2004 Aug) 261 (7) 359-68.
Journal code: 9002937. ISSN: 0937-4477.
PUB. COUNTRY: Germany: Germany, Federal Republic of
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 200409
ENTRY DATE: Entered STN: 20040810
Last Updated on STN: 20041001
Entered Medline: 20040930

AB Squamous cell carcinomas of the head and neck (SCCHN) are excellent
candidates for local immunotherapy owing to their accessibility and their
infiltration by mononuclear cells that are susceptible to
immunomodulation. A response rate of 25-60% has been reported for
treatment with natural IL-2 or a mixture of natural lymphokines. In the
present study, biopsies and posttreatment excision specimens from nine
patients with operable SCCHN treated systemically with a variety of
immunomodulators and locally with natural lymphokines (**multikine**
, CelSci) were analyzed in an attempt to correlate clinical response to
histopathological and immunohistochemical changes. Formalin-fixed,
paraffin-embedded tissues were stained with antibodies against lymphocytes
(CD45, CD3, CD4, CD8, CD20), macrophages (CD68) including dendritic cells
(S-100), markers for lymphocyte activation (CD30, HLA-DR), natural killer
cells (CD56 and CD57), beta-2-microglobulin and keratin. One patient
showed a complete response to treatment and two a partial response. Tumor

size was significantly smaller after therapy. Clinical and pathological regression were more prominent in the smaller tumors. Numerous macrophages, both mononucleated and multinucleated, were present along the tumor-stroma interface in the posttreatment specimens of seven patients, most prominently in the three patients with tumor regression. The increase in the number of CD68+ and S-100+ macrophages after treatment was statistically significant. Lymphocytic infiltrates, which showed some increase following treatment, were composed of a mixture of T and B lymphocytes, the former mostly in contact with the tumor and the latter placed more peripherally. CD8+ lymphocytes extended into the tumors, whereas CD4+ lymphocytes showed minimal extension. Intensity of beta-2-microglobulin staining in tumors was significantly higher following therapy and associated with a better outcome. The marked increase in macrophages following treatment may indicate that the macrophage plays a major role in tumor recognition, destruction and clearance. An increase in the number of macrophages in a posttreatment specimen may indicate immunoresponsiveness.

L2 ANSWER 2 OF 6 MEDLINE on STN DUPLICATE 2
 ACCESSION NUMBER: 2003580296 MEDLINE
 DOCUMENT NUMBER: PubMed ID: 14660929
 TITLE: The effect of leukocyte interleukin injection (**Multikine**) treatment on the peritumoral and intratumoral subpopulation of mononuclear cells and on tumor epithelia: a possible new approach to augmenting sensitivity to radiation therapy and chemotherapy in oral cancer--a multicenter phase I/II clinical Trial.
 AUTHOR: Timar Jozsef; Forster-Horvath C; Lukits J; Dome B; Ladanyi A; Remenar E; Kasler M; Bencsik M; Repassy G; Szabo G; Velich N; Suba Z; Elo J; Balatoni Z; Bajtai A; Chretien P; Talor Eyal
 CORPORATE SOURCE: National Institute of Oncology, Semmelweis University, Budapest, Hungary.
 SOURCE: Laryngoscope, (2003 Dec) 113 (12) 2206-17.
 Journal code: 8607378. ISSN: 0023-852X.
 PUB. COUNTRY: United States
 DOCUMENT TYPE: (CLINICAL TRIAL)
 (CLINICAL TRIAL, PHASE I)
 (CLINICAL TRIAL, PHASE II)
 Journal; Article; (JOURNAL ARTICLE)
 (MULTICENTER STUDY)
 LANGUAGE: English
 FILE SEGMENT: Priority Journals
 ENTRY MONTH: 200401
 ENTRY DATE: Entered STN: 20031216
 Last Updated on STN: 20040109
 Entered Medline: 20040108
 AB OBJECTIVES/HYPOTHESIS: The main objective of this study was to investigate the effect of the administration of a novel immunoadjuvant, leukocyte interleukin injection, as part of an immuno-augmenting treatment regimen on the peritumoral and intratumoral subpopulations of the tumor infiltrating mononuclear cells and on the epithelial and stromal components, when administered to patients with advanced primary oral squamous cell carcinoma classified as T2-3N0-2M0, as compared with disease-matched control patients (not treated with leukocyte interleukin injection). STUDY DESIGN: Multicenter Phase I/II clinical trial. Fifty-four patients from four clinical centers were included in the dose-escalating study (27 in each group [leukocyte interleukin injection-treated and control groups]). Cumulative leukocyte inter-leukin injection doses were 2400, 4800, and 8000 IU (as interleukin-2 equivalent). METHODS: Paraffin-embedded tumor samples obtained at surgical resection of the residual tumor (between days 21 and 28 after treatment initiation) were used. Histological analysis, necrosis evaluation, and American Joint Committee on Cancer grading were performed from H&E-stained sections. Immunohistochemical analysis was performed on

three different tumor regions (surface, zone 1; center, zone 2; and tumor-stroma interface, zone 3). Trichrome staining was used to evaluate connective tissue, and morphometric measurements were made using ImagePro analysis software. Cell cycling was determined by the use of Ki-67 marker. RESULTS: Leukocyte interleukin injection treatment induced a shift from stromal infiltrating T cells toward intraepithelial T cells and posted a significant ($P < .05$) increase in intraepithelial CD3-positive T cells independent of the leukocyte interleukin injection dose, whereas the increase in CD25 (interleukin-2 receptor alpha [IL-2Ralpha])-positive lymphoid cells was significant only at the lowest leukocyte interleukin injection dose ($P < .05$). Furthermore, both low- and medium-dose leukocyte interleukin injection treatment induced a significant ($P < .05$) increase in the number of cycling tumor cells, as compared with control values. CONCLUSION: The results could be highly beneficial for patients with oral squamous cell carcinoma. First, leukocyte interleukin injection treatment induces T-cell migration into cancer nests and, second, noncycling cancer cells may enter cell cycling on administration of leukocyte interleukin injection. This latter effect may modulate the susceptibility of cancer cells to radiation therapy and chemotherapy. The findings may indicate a need to re-evaluate the way in which follow-up treatment (with radiation therapy and chemotherapy) of patients with head and neck cancer is currently approached.

L2 ANSWER 3 OF 6 MEDLINE on STN DUPLICATE 3
 ACCESSION NUMBER: 2003388086 MEDLINE
 DOCUMENT NUMBER: PubMed ID: 12925348
 TITLE: Report of a clinical trial in 12 patients with head and neck cancer treated intratumorally and peritumorally with **multikine**.
 AUTHOR: Feinmesser Raphael; Hardy Britta; Sadov Rima; Shwartz Ariel; Chretien Paul; Feinmesser Meora
 CORPORATE SOURCE: Department of Otolaryngology and Head and Neck Surgery, Rabin Medical Center, Petah Tiqwa, Israel.. feinmesserr@clalit.org.il
 SOURCE: Archives of otolaryngology--head & neck surgery, (2003 Aug) 129 (8) 874-81.
 Journal code: 8603209. ISSN: 0886-4470.
 PUB. COUNTRY: United States
 DOCUMENT TYPE: (CLINICAL TRIAL)
 Journal; Article; (JOURNAL ARTICLE)
 LANGUAGE: English
 FILE SEGMENT: Abridged Index Medicus Journals; Priority Journals
 ENTRY MONTH: 200310
 ENTRY DATE: Entered STN: 20030820
 Last Updated on STN: 20031003
 Entered Medline: 20031002

AB BACKGROUND: There is cumulative evidence suggesting that cells of the immune system recognize and may participate in eradicating neoplastic cells. As a result, immune modulation, first with interleukin 2 and later with other cytokines, has been tried in the clinical setting as part of antitumor therapy. OBJECTIVE: To examine the effectiveness and toxicity of a combination of natural interleukins in patients with squamous cell head and neck cancer. METHODS: Twelve previously untreated patients with various head and neck cancers were treated by peritumoral injection of a combination of cytokines (**Multikine**), in addition to zinc sulfate, indomethacin, and a single dose of cyclophosphamide, which were administered systemically. Response was evaluated clinically and histopathologically. T-lymphocyte determinants were studied by fluorescence-activated cell sorter analysis (against controls). RESULTS: Two patients showed complete regression and another 2 showed partial regression. There were no serious adverse effects of treatment. Pathological study results showed tumor fragmentation and the appearance of multinucleated macrophages. Fluorescence-activated cell sorter analysis showed lymphocyte activation, reflected by an unusually high number of cytotoxic T-lymphocyte activation 4 cells and natural killer

cells. CONCLUSION: **Multikine** warrants further investigation for inclusion in the pharmacotherapeutic armamentarium of head and neck cancer.

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ACCESSION NUMBER: 1998140425 EMBASE
TITLE: [Report from the USA].
BERICHT AUS USA.
AUTHOR: Gakenheimer W.C.
CORPORATE SOURCE: Dr. W.C. Gakenheimer, 413 Stafford Road, Wilmington, DE
19803, United States
SOURCE: Pharmazeutische Industrie, (1998) 60/3 (225-229).
ISSN: 0031-711X CODEN: PHINAN
COUNTRY: Germany
DOCUMENT TYPE: Journal; Article
FILE SEGMENT: 036 Health Policy, Economics and Management
037 Drug Literature Index
039 Pharmacy
LANGUAGE: German

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ACCESSION NUMBER: 97116392 EMBASE
DOCUMENT NUMBER: 1997116392
TITLE: Summary of the epidemiological situation concerning
malignancies in the province of Vojvodina in the period
1985 to 1994.
AUTHOR: Mikov M.; Vranjes N.
SOURCE: Archive of Oncology, (1997) 5/1 (33-34).
ISSN: 0354-2351 CODEN: ARONFV
COUNTRY: Yugoslavia
DOCUMENT TYPE: Journal; Note
FILE SEGMENT: 016 Cancer
017 Public Health, Social Medicine and Epidemiology
037 Drug Literature Index
LANGUAGE: English

L2 ANSWER 6 OF 6 MEDLINE on STN DUPLICATE 4

ACCESSION NUMBER: 95378562 MEDLINE
DOCUMENT NUMBER: PubMed ID: 7650289
TITLE: Leukocyte Interleukin, Inj. (LI) augmentation of natural
killer cells and cytolytic T-lymphocytes.
AUTHOR: Chirigos M A; Talor E; Sidwell R W; Burger R A; Warren R P
CORPORATE SOURCE: CEL-SCI Corporation, Alexandria, VA 22314, USA.
SOURCE: Immunopharmacology and immunotoxicology, (1995 May) 17 (2)
247-64.
Journal code: 8800150. ISSN: 0892-3973.
PUB. COUNTRY: United States
DOCUMENT TYPE: Journal; Article; (JOURNAL ARTICLE)
LANGUAGE: English
FILE SEGMENT: Priority Journals
ENTRY MONTH: 199509
ENTRY DATE: Entered STN: 19951005
Last Updated on STN: 19951005
Entered Medline: 19950927

AB A serum free lymphokine preparation derived from human buffy-coat mononuclear cells [buffy coat interleukins (BC-IL)], also named Leukocyte Interleukin, Inj. (LI), trade name **Multikine**, containing glycosylated interleukin-2 (IL-2) among other interleukins, was tested in three head and neck cancer patients. They responded with tumor regressions associated with increased tumor infiltration of lymphocytes and tumor cell lysis indicating an LI Interleukin-2 induced tumor-specific immune response. To determine whether these responses elicited by LI were IL-2 driven, augmentation of natural killer cells (NKC) and cytolytic T

cells (CTL), was tested both in vitro and in vivo. A single intraperitoneal (i.p.) injection of LI in adult BALB/c mice at doses of 3, 10, 30 and 100 of IL-2 equivalence International Units per mouse, led to significant ($p < 0.01$) augmentation of NKC cytotoxicity to YAC tumor cells. NKC cytotoxicity remained elevated for 7 days, peaking at 5 days post-treatment. Multiple treatments with LI did not increase NKC cytotoxicity above single injection, nor did it lead to NKC hyporesponsiveness. The most effective treatment routes leading to heightened NKC cytotoxicity were: intravenous(i.v.) > intraperitoneal (i.p.) > intramuscular (i.m.) > subcutaneous (sc). Significant ($p < 0.05$ to < 0.01) NKC cytotoxicity was achieved by all four routes. In vitro incubation of murine splenocytes with 30 and 100 International Units/ml (IU/ml) of IL-2 equivalent elevated NKC cytotoxicity significantly ($p < 0.01$) at all effector to target cell ratios tested and exceeded the response achieved with rhIFN gamma. NKC cytotoxicity of human peripheral blood lymphocytes (HPBL) against the K562 human tumor cell was also significantly elevated ($p < 0.01$) at the 30 and 100 IU/ml doses and ($p < 0.05$) at 3 and 10 IU/ml doses. Of particular interest was the significant increase of CTL response in HPBL generated by LI. Significant activity ($p < 0.01$) was achieved with levels of 10, 30 and 100 IU/ml at effector to target cell ratios as low as 6 to 1. These results indicate that the LI containing IL-2 led to the significant increase in NKC and CTL cytolytic activities. Relatively lower doses of LI were needed to attain equivalent cytolytic activities as achieved with rhIL-2 or rhIFN gamma.

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FULL ESTIMATED COST

SINCE FILE ENTRY	TOTAL SESSION
0.21	0.21

FILE 'EUROPATFULL' ENTERED AT 10:03:20 ON 18 NOV 2004
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MOST RECENT EPO WEEK: 200447 <200447/EW>
FILE COVERS 1987 TO DATE

>>>>The LIMIT feature has been removed <<<<

=> s multikine
0 MULTIKINE
L1 0 MULTIKINE

=> s pctfull
0 PCTFULL
L2 0 PCTFULL

=> file pctfull
COST IN U.S. DOLLARS

SINCE FILE ENTRY	TOTAL SESSION
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FULL ESTIMATED COST

1.71

1.92

FILE 'PCTFULL' ENTERED AT 10:03:45 ON 18 NOV 2004

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FILE LAST UPDATED: 17 NOV 2004 <20041117/UP>

MOST RECENT UPDATE WEEK: 200446 <200446/EW>

FILE COVERS 1978 TO DATE

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=> s multikine

L3 6 MULTIKINE

=> d ibib kwic 1-6

L3 ANSWER 1 OF 6 PCTFULL COPYRIGHT 2004 Univentio on STN
ACCESSION NUMBER: 2004033665 PCTFULL ED 20040427 EW 200417
TITLE (ENGLISH): HETEROLOGOUS PLASMA COCKTAIL FOR HIV TREATMENT
TITLE (FRENCH): COCKTAIL DE PLASMA HETEROLOGUE UTILISE DANS LE
TRAITEMENT DU VIH
INVENTOR(S): TOLETT, Malcolm, A., 1777 Union Ave., Niceville, FL
32578, US
PATENT ASSIGNEE(S): IMUTEX PHARMACEUTICALS, INC., 402 W. Broadway, Fourth
Floor, San Diego, CA 92101, US [US, US], for all
designates States except US
AGENT: KNOWLES, Sherry, M.\$, King & Spalding, 191 Peachtree
Street, Atlanta, GA 30303-1763\$, US
LANGUAGE OF FILING: English
LANGUAGE OF PUBL.: English
DOCUMENT TYPE: Patent
PATENT INFORMATION:

NUMBER KIND DATE

WO 2004033665 A2 20040422

DESIGNATED STATES

W:

AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR
CU CZ DE DK DM DZ EC EE EG ES FI GB GD GE GH GM HR HU
ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA
MD MG MK MN MW MX MZ NI NO NZ OM PG PH PL PT RO RU SC
SD SE SG SK SL SY TJ TM TN TR TT TZ UA UG UZ VC VN YU
ZA ZM ZW

RW (ARIPO): GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW

RW (EAPO): AM AZ BY KG KZ MD RU TJ TM

RW (EPO): AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IT LU
MC NL PT RO SE SI SK TR

RW (OAPI): BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG

APPLICATION INFO.: WO 2003-US32517 A 20031014

PRIORITY INFO.: US 2002-60/418,136 20021011

DETD . . . (IL-2, Aldesleukin, Proleukin, Chiron Corporation). IL-2 is often used in combination with antiretroviral drugs or and during therapeutic breaks from antiretroviral therapy. **Multikine** (Cel-Sci Corporation) is a mixture of several different cytokines.

L3 ANSWER 2 OF 6 PCTFULL COPYRIGHT 2004 Univentio on STN
 ACCESSION NUMBER: 2003035004 PCTFULL ED 20030512 EW 200318
 TITLE (ENGLISH): IMMUNOTHERAPY FOR REVERSING IMMUNE SUPPRESSION
 TITLE (FRENCH): IMMUNOTHERAPIE DE RETABLISSEMENT D'IMMUNITE SUPPRIMEE
 INVENTOR(S): HADDEN, John, W., 428 Harbor Road, Cold Spring Harbor,
 NY 11724, US [US, US]
 PATENT ASSIGNEE(S): IMMUNO-RX, INC., 140 West 57th Street, Suite 9C, New
 York, NY 10019, US [US, US], for all designates States
 except US;
 HADDEN, John, W., 428 Harbor Road, Cold Spring Harbor,
 NY 11724, US [US, US], for US only
 AGENT: KOHN, Kenneth, I.\$, Kohn & Associates, Suite 410, 30500
 Northwestern Highway, Farmington Hills, MI 48334\$, US
 LANGUAGE OF FILING: English
 LANGUAGE OF PUBL.: English
 DOCUMENT TYPE: Patent
 PATENT INFORMATION:

NUMBER	KIND	DATE
WO 2003035004	A2	20030501

DESIGNATED STATES

W: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR
 CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID
 IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD
 MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI
 SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
 RW (ARIPO): GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW
 RW (EAPO): AM AZ BY KG KZ MD RU TJ TM
 RW (EPO): AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LU MC
 NL PT SE SK TR
 RW (OAPI): BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG

APPLICATION INFO.: WO 2002-US34361 A 20021026
 PRIORITY INFO.: US 2001-60/344,509 20011026

DETD and neck cancer, tumoral injection of
 recombinant interleukin-2 produced a T cell lymphocyte infiltrate, but
 without
 significant clinical responses. Peritumoral injection of
Multikine (Celsci website)
 in combination with perilymphatic injection in up to 150 patients
 resulted in
 significant tumor responses, i.e., greater than 50% tumor.

L3 ANSWER 3 OF 6 PCTFULL COPYRIGHT 2004 Univentio on STN
 ACCESSION NUMBER: 2003025575 PCTFULL ED 20030402 EW 200313
 TITLE (ENGLISH): METHODS AND COMPOSITIONS INVOLVING THYMIDINE
 PHOSPHORYLASE AS A MARKER FOR HIV INFECTION, AIDS
 PROGRESSION, AND DRUG RESISTANCE
 TITLE (FRENCH): METHODES ET COMPOSITIONS UTILISANT LA THYMIDINE
 PHOSPHORYLASE COMME MARQUEUR DE L'INFECTION VIH, DE
 L'EVOLUTION DU SIDA ET DE LA RESISTANCE AUX MEDICAMENTS
 INVENTOR(S): CLOYD, Miles, W., 12420 East Ventura St., Galveston, TX
 77554, US [US, US];
 CHEN, Jenny, 431 South 45th Street, Philadelphia, PA
 19104, US [US, US];
 WANG, Liqiang, 7685 Chantilly Circle, Galveston, TX
 77551, US [US, US];
 LEE, Kyeongeun, P.O. Box 241982, Galveston, TX 77555,
 US [US, KR];
 PAAR, David, 1509 Sealy Street, Galveston, TX 77550, US
 [US, US]
 PATENT ASSIGNEE(S): BOARD OF REGENTS, The University of Texas System, 201
 West 7th Street, Austin, TX 78701, US [US, US], for all
 designates States except US;

CLOYD, Miles, W., 12420 East Ventura St., Galveston, TX 77554, US [US, US], for US only;
CHEN, Jenny, 431 South 45th Street, Philadelphia, PA 19104, US [US, US], for US only;
WANG, Liqiang, 7685 Chantilly Circle, Galveston, TX 77551, US [US, US], for US only;
LEE, Kyeongeun, P.O. Box 241982, Galveston, TX 77555, US [US, KR], for US only;
PAAR, David, 1509 Sealy Street, Galveston, TX 77550, US [US, US], for US only

AGENT: SHISHIMA, Gina, N.\$, Fulbright & Jaworski, L.L.P., Suite 2400, 600 Congress Avenue, Austin, TX 78701\$, US
LANGUAGE OF FILING: English
LANGUAGE OF PUBL.: English
DOCUMENT TYPE: Patent
PATENT INFORMATION:

NUMBER	KIND	DATE
WO 2003025575	A1	20030327

DESIGNATED STATES

W:

AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR
CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID
IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD
MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI
SK SL TJ TM TN TR TT TZ UA UG US UZ VC VN YU ZA ZM ZW

RW (ARIPO): GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW

RW (EAPO): AM AZ BY KG KZ MD RU TJ TM

RW (EPO): AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LU MC
NL PT SE SK TR

RW (OAPI): BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG

APPLICATION INFO.: WO 2002-US29397 A 20020916
PRIORITY INFO.: US 2001-60/322,791 20010917

DETD . . . Enzo Therapeutics. Finally, immune stimulators may be employed as a therapeutic regimen against HIV and IRV disease (AIDS). IIL-2 (Aidesleukine, Proleuking), Reticulose, **Multikine**, Ampligen, HE2000, and HIV-1 Immunogen (Remune 0) are example of immune stimulators.

L3 ANSWER 4 OF 6

ACCESSION NUMBER:

TITLE (ENGLISH):

TITLE (FRENCH):

INVENTOR(S):

PCTFULL COPYRIGHT 2004 Univentio on STN
2003021223 PCTFULL ED 20030319 EW 200311
METHODS FOR QUALITATIVE AND QUANTITATIVE ANALYSIS OF
CELLS AND RELATED OPTICAL BIO-DISC SYSTEMS
TECHNIQUE D'ANALYSE QUALITATIVE ET QUANTITATIVE DE
CELLULES ET SYSTEMES DE DISQUES OPTIQUES BIOLOGIQUES
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LANGUAGE OF FILING: English

LANGUAGE OF PUBL.: English

DOCUMENT TYPE: Patent

PATENT INFORMATION:

NUMBER	KIND	DATE
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	WO 2003021223	A2 20030313
DESIGNATED STATES		
W:	AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG UZ VN YU ZA ZM ZW	
RW (ARIPO):	GH GM KE LS MW MZ SD SL SZ TZ UG ZM ZW	
RW (EAPO):	AM AZ BY KG KZ MD RU TJ TM	
RW (EPO):	AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LU MC NL PT SE SK TR	
RW (OAPI):	BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG	
APPLICATION INFO.:	WO 2002-US27762	A 20020830
PRIORITY INFO.:	US 2001-60/315,937	20010830
	US 2001-60/328,246	20011010
	US 2001-60/386,072	20011019
	US 2001-60/386,073	20011019
	US 2001-60/386,071	20011026
	US 2001-60/344,977	20011107
	US 2001-60/338,679	20011113
	US 2001-09/988,728	20011120
	US 2001-60/334,131	20011130
	US 2002-60/355,644	20020205
	US 2002-60/358,479	20020219

DETD 7. Immune Stimulators, use the body's chemical messengers to stimulate the immune response. Interleukin 2 (11-2, Aldesleukin, Proleukin, Reficulose and **Multikine** and an inactivated virus preparation, HIV-1 Immunogen, is in Phase III trials.

L3 ANSWER 5 OF 6 PCTFULL COPYRIGHT 2004 Univentio on STN
 ACCESSION NUMBER: 2002064096 PCTFULL ED 20020904 EW 200234
 TITLE (ENGLISH): METHODS OF USING PYRIMIDINE-BASED ANTIVIRAL AGENTS
 TITLE (FRENCH): PROCEDES D'UTILISATION D'AGENTS ANTIVIRAUX A BASE DE PYRIMIDINE
 INVENTOR(S): JAEN, Juan, C., 154 Los Robles Drive, Burlingame, CA 94010, US [US, US]
 PATENT ASSIGNEE(S): TULARIK INC., Two Corporate Drive, South San Francisco, CA 94080, US [US, US], for all designates States except US;
 JAEN, Juan, C., 154 Los Robles Drive, Burlingame, CA 94010, US [US, US], for US only
 AGENT: KEZER, William, B.\$, Townsend And Townsend And Crew LLP, Two Embarcadero Center, Eighth Floor, San Francisco, CA 94111\$, US
 LANGUAGE OF FILING: English
 LANGUAGE OF PUBL.: English
 DOCUMENT TYPE: Patent
 PATENT INFORMATION:

NUMBER	KIND	DATE
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WO 2002064096	A2	20020822

DESIGNATED STATES	
W:	AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW
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RW (EAPO):	AM AZ BY KG KZ MD RU TJ TM
RW (EPO):	AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
RW (OAPI):	BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG

APPLICATION INFO.: WO 2002-US4920 A 20020214
PRIORITY INFO.: US 2001-60/269,778 20010216

DETD . . . (13ristol-Myers Squibb), tipranavir, DNT-450
(Triangle Pharmaceuticals), and lopinavir and (d) immune stimulators
such as interleukin
2 (Chiron), Reticulose' (Advance Viral Research Corporation);
Multikine (Cel-Sci
Corporation), and HIV-1 immunogen (Immune Response Corporation). Other
anti-111V
agents that may be used in combination with the compounds and
compositions. . .

L3 ANSWER 6 OF 6 PCTFULL COPYRIGHT 2004 Univentio on STN
ACCESSION NUMBER: 2002034119 PCTFULL ED 20020515 EW 200218
TITLE (ENGLISH): VACCINE IMMUNOTHERAPY FOR IMMUNE SUPPRESSED PATIENTS
TITLE (FRENCH): IMMUNOTHERAPIE VACCINALE POUR PATIENTS IMMUNODEPRIMES
INVENTOR(S): HADDEN, John, W., 428 Harbor Road, Cold Spring Harbor,
NY 11724, US [US, US]
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York, NY 10019, US [US, US], for all designates States
except US;
HADDEN, John, W., 428 Harbor Road, Cold Spring Harbor,
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AGENT: KOHN, Kenneth, I.\$, Kohn & Associates, 30500
Northwestern Hwy., Suite 410, Farmington Hills, MI
48334\$, US
LANGUAGE OF FILING: English
LANGUAGE OF PUBL.: English
DOCUMENT TYPE: Patent
PATENT INFORMATION:

NUMBER	KIND	DATE
WO 2002034119	A2	20020502

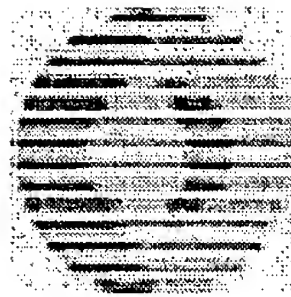
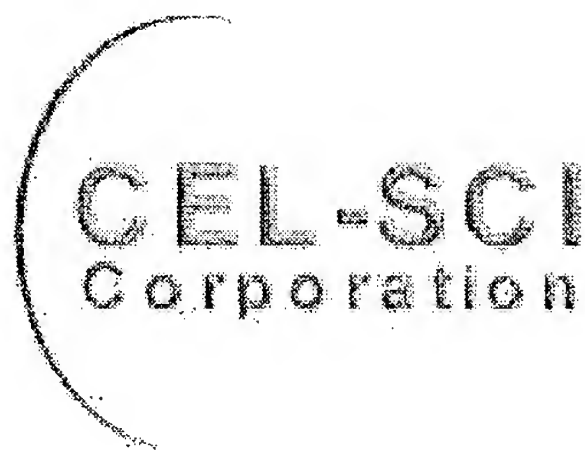
DESIGNATED STATES

W: AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR
CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID
IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD
MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL
TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW
RW (ARIPO): GH GM KE LS MW MZ SD SL SZ TZ UG ZW
RW (EAPO): AM AZ BY KG KZ MD RU TJ TM
RW (EPO): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
TR
RW (OAPI): BF BJ CF CG CI CM GA GN GQ GW ML MR NE SN TD TG

APPLICATION INFO.: WO 2001-US48039 A 20011026
PRIORITY INFO.: US 2000-60/243,912 20001027

DETD . . . neck cancer, tumoral injection of recombinant interleukin-
2 produced a T cell lymphocyte infiltrate, but without significant
clinical
responses. Peritumoral injection of **Multikine** (CeIsci
Website) (in
combination with perilymphatic injection in up to 150 patients resulted
in
12
significant tumor responses, i.e. greater than 50% tumor. . .

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- investor relations

RECENT WEBCAST EVENTS

June 22, 2004, 2:00 pm Eastern
American Stock Exchange (AMEX)
Healthcare/Biotech Investor Conference
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February 23 - 25, 2004
6th Annual BIO CEO & Investor Conference
New York, New York
[Click here to listen](#)

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Overshadowed so quickly by the issue of the ever-changing stock price is the fact that there still exists a great need for a drug that will enhance the cure rate of the first cancer treatment. The company that succeeds in addressing that need will leave its shareholders very happy and help huge numbers of patients. Our immunotherapy drug Multikine has shown results that may make this important goal possible, initially in head & neck cancer, and later on hopefully in other cancers too since Multikine is not tumor specific. To highlight what CEL-SCI has accomplished, let me reiterate the key findings with Multikine:

- 1) Phase II clinical trial data published by CEL-SCI in the *Proceedings of the 40th ASCO Annual Meeting*, June 5-8, 2004, describe a new, and seemingly more effective, way of activating a patient's immune response against cancer. This new finding may enable physicians to direct the immune response of a cancer patient in a way that defeats the tumor's defenses. The study showed a 42% response rate with a 12% cure rate after only three weeks of treatment prior to the standard therapy, surgery and radiation. We believe that the addition of this response to the clinical benefit conferred by surgery and radiation will increase the overall success rate seen in a combined therapy of Multikine/surgery/radiation when compared to surgery and radiation alone.
- 2) The publication of a clinical trial with Multikine in *The Laryngoscope* in December 2003 showed that Multikine may significantly increase the "kill rate" of cancer cells through radiation. This alone may make the surgery/radiation treatment more successful.
- 3) Follow-up data on disease recurrence is currently available for only 8 of the 27 patients treated with Multikine. For these 8 patients who were sequentially treated at one center, no disease recurrence was observed at 24 months post treatment. This contrasts with the scientific literature which reports that up to 50% of primary head and neck cancer patients will have a recurrence of the cancer within 18 to 24 months after surgery and/or radiation therapy.
- 4) Multikine has an excellent safety profile.
- 5) Additional papers will give more information.

LETTER TO SHAREHOLDERS

RECEIVE CEL-SCI'S NEWS RELEASES VIA E-MAIL

American Stock Exchange Common Stock Symbol: CVM

Thank you for taking the time to learn more about our commitment to develop innovative drugs for the future

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When used in this report, the words "intends," "believes," "anticipates," "plans" and "expects" and similar expressions are intended to identify forward-



**Read how
CEL-SCI is
reaching
its goals**

Factors that could cause or contribute to such differences include an inability to duplicate the results demonstrated in clinical studies, timely development of any potential products that can be shown to be safe and effective, the inability to raise the necessary financing for the company, receiving necessary regulatory approvals, difficulties in manufacturing any of the Company's potential products and the risk factors set forth from time to time in CEL-SCI corporation's SEC filings, including but not limited to its report on Form 10-K/A for the year ended September 30, 2003. The Company undertakes no obligation to publicly release the result of any revision to these forward-looking statements which may be made to reflect the events or circumstances after the date thereof or to reflect the occurrence of unanticipated events.

Multikine® is an immunotherapeutic agent consisting of a mixture of naturally occurring cytokines including interleukins, interferons, chemokines and colony-stimulating factors. As a neo-adjuvant, Multikine has induced tumor reduction and tumor necrosis in Phase II trials of head & neck cancer. Multikine is nontoxic and offers a diverse and possibly synergistic cytokine profile believed to play an important role in local and regional and possible systemic immune restoration. Multikine appears to boost the patient's immune system and break tumor tolerance.

[Tumor Pictures](#)

L.E.A.P.S.™ is a patented, T-cell modulation, peptide epitope delivery technology that enables CEL-SCI to design and synthesize proprietary peptide immunogens. L.E.A.P.S. compounds consist of a small T-cell binding peptide ligand linked with a disease-associated peptide antigen. This new technology has been shown in several animal models to preferentially direct immune response to a cellular (e.g. T-cell), humoral (antibody) or mixed pathway. Any disease for which antigenic epitope sequences have been identified, such as infectious diseases, cancer, autoimmune diseases, allergic asthma and allergy, and select CNS diseases (e.g., Alzheimer's) are potential candidates for this technology platform. The leading product candidate that has been developed from this technology is the CEL-1000 peptide. This peptide has shown protection in animals against malaria, herpes and cancer. This data was recently presented at a scientific meeting by U.S. Navy researchers. Most of the L.E.A.P.S. research and development is supported by grants.

[L.E.A.P.S. Scientific Backgrounder](#)

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